Complete Summary

GUIDELINE TITLE

Fibromyalgia treatment guideline.

BIBLIOGRAPHIC SOURCE(S)

University of Texas, School of Nursing, Family Nurse Practitioner Program. Fibromyalgia treatment guideline. Austin (TX): University of Texas, School of Nursing; 2005 May. 13 p. [18 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Fibromyalgia

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine

Nursing
Rheumatology
Sleep Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians

GUIDELINE OBJECTIVE(S)

- To guide practice decisions that integrate medical, pharmacological, and behavioral elements for treatment
- To enhance the quality and functionality of life for the patient
- To interpret and integrate the latest research to effectively manage patients with fibromyalgia
- To delineate the criteria for definite diagnosis and treatment
- To obtain the highest level of patient compliance and satisfaction with therapeutic and pharmacologic management

TARGET POPULATION

Women, age 50 to 65 years old who meet the diagnostic criteria for fibromyalgia syndrome, including widespread pain of more than 3 months duration in all four quadrants of their body and pain present in at least 11 of the 18 specified tender points

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Subjective assessment, including history, comorbid conditions, and symptoms
2. Physical examination, including vital signs, bilateral digital palpitation, and Fibromyalgia Impact Questionnaire
3. Diagnostic laboratory tests
    - Comprehensive metabolic panel (CMP)
    - Complete blood count (CBC)
    - Thyroid-stimulating hormone (TSH) measurement
    - Triiodothyronine (T3) and thyroxine measurement
    - Sedimentation rate
    - Liver panel
    - Creatinine phosphokinase measurement
4. Psychological analysis
5. Musculoskeletal assessment
6. Neurological assessment
7. Attended in-laboratory polysomnography

Treatment/Management

1. Patient and family education
2. Pharmacological treatment
    - Tricyclic antidepressants (TCAs) (i.e., amitriptyline), cyclobenzaprine, or benzodiazepines to ensure adequate sleep
    - Addition of selective serotonin reuptake inhibitor (SSRI) (i.e., fluoxetine) to tricyclic antidepressant to treat fatigue and depression
    - Cyclobenzaprine or low-dose benzodiazepine (i.e., clonazepam) to treat muscle spasms
    - Tramadol for pain control

    Note: Non-steroidal anti-inflammatory agents and opioids were considered, but not recommended.

3. Non-pharmacological treatment
    - Exercise and massage
    - Tender or trigger point injections
    - Referral to appropriate specialty (i.e., psychotherapy)

MAJOR OUTCOMES CONSIDERED

- Quality of life
- Level of pain
- Sleep
- Muscle strength
- Physical mobility
- Daily activity functioning

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The following resources were reviewed:

1. Nationally recognized, expert standards established by the American College of Rheumatology Diagnostic Criteria
2. Nationally recognized, expert association literature obtained from the American Medical Association, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS). and the U.S. Department of Health and Human Services

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Subjective Review
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Level I: Evidence obtained from at least one properly randomized-controlled trial

Level II-1: Evidence obtained from well-designed control trials without randomization

Level II-2: Evidence obtained from well-designed cohort or case-controlled analytic studies, preferably from more than one center or research group

Level III: Opinions of respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Articles were reviewed for applicability for target population and for validity and reliability of research methods and results.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Synthesis and interpretation of the latest guidelines and research

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Recommendations

A. There is good evidence to support the recommendation.
B. There is fair evidence to support the recommendation.
C. There is insufficient evidence to recommend for or against, but recommendations may be made on other grounds.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A draft of the guideline was developed by a group of family nurse practitioner (FNP) students and submitted for review to the family nurse practitioner faculty. A final review was performed by an external expert, and subsequent changes were made prior to submitting to guidelines committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Levels of evidence (I, II-1, II-2, and III) and recommendation grades (A-C) are defined at the end of the "Major Recommendations" field.

Subjective Assessment

History

1. Assessment of nature of pain, intensity, location, onset, aggravating and relieving factors
2. Assessment of functionality
3. Assessment of sleep disturbances and persistent fatigue
4. Trauma history
5. Gynecological history
6. Assessment of comorbid conditions such as:
    - Migraine or tension headaches
    - Dysmenorrhea
    - Irritable bowel syndrome
    - Restless leg syndrome
    - Depression
    - Anxiety
    - Sicca syndrome (Sjogren's syndrome)
    - Cognitive or memory impairment
    - Female urethral syndrome

Symptoms

1. Musculoskeletal symptoms:
    - Widespread pain at multiple sites
    - Stiffness

- Sensation of hurting all over
- Diffuse soft tissue swelling

2. Non-musculoskeletal symptoms:
    - Fatigue
    - Morning fatigue
    - Sleep difficulties
    - Paresthesias

Past Medical History

1. Note hospitalizations, surgeries, and/or procedures

Medication History

1. Current prescription medications
2. Any and all over-the-counter medications, including alternative medicines or herbal treatments
3. Ascertain previous fibromyalgia treatment (i.e., sleeping pills, selective serotonin reuptake inhibitors [SSRIs], tricyclic antidepressants [TCAs], pain medications, including narcotics) and note response.

Family History

1. Rheumatoid arthritis
2. Systemic lupus erythematosus
3. Osteoarthritis
4. Hypothyroidism
5. Psychological disorders (i.e., depression, psychosis, anxiety)
6. Raynaud's phenomena/disease
7. Irritable bowel syndrome
8. Migraine headaches

Psychosocial History

1. Evaluate pain and coping skills using appropriate screening tools such as the Chronic Pain Coping Inventory (CPCI) (Nielson & Jensen, 2004).
2. Evaluate availability of support systems (i.e., financial support, insurance, Social Security Disability Insurance [SSDI], Medical or disability).
3. Elicit occurrence of any traumatic or stressful life events and the possible relation of symptoms to these events.
4. Assessment of lifestyle choices (i.e. exercise, alcohol, caffeine, tobacco, illicit drug use)
5. Impact of symptoms on the patient's family, interpersonal relationships, work, school, and activities of daily living
6. Psychosocial history including depression and suicidal ideation evaluation

Objective Assessment

Physical Examination

1. Measure vital signs.

2. Observe general appearance.
3. Assess neck for thyromegaly.
4. Perform bilateral digital palpitation using a force of about 4 kg, which is approximately equal to pressing finger on bathroom scale until it registers 10 pounds, or until the nail bed just begins to blanch; to meet criteria of a positive tender point, patient must label the palpation as "painful", not just tender (Wolfe et al., 1990).
5. Perform a complete musculoskeletal examination, assessing each joint separately.
6. Neurologic assessment
7. Assess mental status and perform a mental health assessment.
8. Fibromyalgia Impact Questionnaire (FIQ) - see www.myalgia.com/FIQ/fiq.pdf

Diagnostic Procedures

1. Laboratory tests: comprehensive metabolic panel (CMP), complete blood count (CBC), thyroid-stimulating hormone (TSH), triiodothyronine (T3), thyroxine (T4), sedimentation rate, liver panel, creatinine phosphokinase
2. Psychological analysis: depression scale, suicidal ideation assessment
3. Sleep analysis

Criteria for Diagnosis

1. History of widespread pain present for at least 3 months: Pain is considered widespread when all of the following are present:
    - Pain in the left and right side of the body
    - Pain above and below the waist
    - Axial skeletal pain (cervical spine, anterior chest, thoracic spine, or low back)
    - Shoulder and buttock pain is considered as pain for each involved side.
    - Low back pain is considered lower segment.
2. Presence of 11 out of 18 paired, bilateral tender points as delineated by the American College of Rheumatology (Wolfe et. al., 1990)
    - Occiput: bilateral, at the suboccipital muscle insertions
    - Low cervical: bilateral, at the anterior aspects of the intertransverse spaces at C5-C7
    - Trapezius: bilateral, at the midpoint of the upper border
    - Supraspinatus: bilateral, originating above the scapula spine near the medial border
    - Second rib: bilateral, at the second costochondral junctions
    - Lateral epicondyle: bilateral, 2 cm distal to the epicondyles
    - Gluteal: bilateral, in upper outer quadrants in anterior fold of muscle
    - Greater trochanter: bilateral, posterior to the trochanteric prominence
    - Knee: bilateral, at the medial fat pad proximal to the joint line

Differential Diagnosis

1. Chronic fatigue syndrome
2. Rheumatoid arthritis
3. Sjogren's syndrome
4. Systemic lupus erythematosus
5. Ankylosing spondylitis

6. Polymyalgia rheumatica
7. Inflammatory myositis
8. Metabolic myopathies
9. Hypothyroidism
10. Hyperparathyroidism
11. Cushing's syndrome

Step 1 - Patient and Family Education

1. Validate the diagnosis. Patients need to understand their illness before any medications can be prescribed. They must be reassured that fibromyalgia is a "real" illness (Goldenberg, 2004). (Level III, Recommendation C)
2. Educate about prognosis, pathophysiology, and treatment principles. Lectures, group discussions, and written materials improved outcomes including pain, sleep, fatigue, self efficacy, and quality of life (Goldenberg, Burekhardt, & Crofford, 2004) (Level I, Recommendation A)
3. Fibromyalgia Impact Questionnaire (FIQ). FIQ is a tool to quantitate fibromyalgia's impact over several dimensions of the patient's life, such as function, pain level, fatigue, sleep deprivation, and psychological distress. It is scored from 0 to 100, with 100 being the worst case scenario, with the average being 50 in patients seen in primary care clinics. This tool can be used to monitor the effect of interventions and evaluate patient functional status.

Step 2 - Pharmacological Treatment

1. Adequate sleep. It is proposed that sleep disturbance occurs from a variety of reasons. Some of these reasons include serotonin metabolism in the central nervous system (CNS), resulting in low levels of brain serotonin, low levels of growth hormone secretion, and generalized body pain from the disease process. TCAs help promote restorative sleep and heighten the effects of the body's natural pain-killing substances (endorphins), and increases non-rapid eye movement (non-REM) stage 4 sleep. Low levels of serotonin and norepinephrine are related to depression, muscle pain, and fatigue. Administering TCAs such as amitriptyline helps correct these deficiencies. Recommended dosing is as follows: Amitriptyline 25-50 mg 2 to 3 hours before bedtime, allowing peak sedative effect with minimal carry-over effect. May increase dosing to 50-75 mg over the next weeks if needed for added control. Cyclobenzaprine can be used as an alternative to amitriptyline because of its structural similarity to TCA compounds. The dosage is 10-30 mg at bedtime (QHS). Benzodiazepines are a second alternative, but should be used cautiously at bedtime due to their tendency to stabilize the erratic brain waves that interfere with restorative sleep in patients with fibromyalgia. (Millea & Holloway, 2000) (Level I, Recommendation A)
2. Treat fatigue and depression. If no response with TCAs, consider adding selective serotonin reuptake inhibitor (fluoxetine) in the morning. Dosing for fluoxetine is 20 mg every morning (QAM). This class of drugs works to block the re-uptake of serotonin, which in turn allows the body to utilize greater amounts of serotonin. The exact mechanism of action for fluoxetine in fibromyalgia syndrome is unknown. Since people with fibromyalgia already have decreased levels of serotonin; it is believed that fluoxetine increases the levels of serotonin to the brain. (Note: One research study completed in 2002

found there is a synergistic effect between fluoxetine and amitriptyline due to the pharmacokinetic interaction between the 2 drugs. Using them together may be more effective for the patient's symptoms than using them alone) (Arnold et al., 2002) (Level I, Recommendation A)

3. Treat muscle spasms. Cyclobenzaprine or low dose benzodiazepines (clonazepam) are used to treat muscle spasms. See explanation above for pathophysiological effect of these medications. Cyclobenzaprine also modulates muscle tension at a supraspinal level. Dosing is 10-30 mg every day (QD) or, if greater dosing is needed, divide the doses, with the smaller dose in the morning and the larger dose in the evening (Tofferi, Jackson, & O'Malley, 2004). (Level I, Recommendation A)
4. Adequate pain control. The pain component of fibromyalgia is thought to be abnormal CNS processing of pain signals. It is thought that the pain is caused by a complex interaction between neurotransmitter release, external stressors, patient behavior, hormones, and the CNS system. Tramadol 50-100 mg every 4 to 6 hours is recommended for pain control. Non-steroidal anti-inflammatory agents are not recommended because fibromyalgia is not an anti-inflammatory process. Opioids are not recommended due to adverse side effects and regulatory concerns, and no increased benefit has been noted in research studies (Inanici & Yunus, 2002). (Level I, Recommendation A)

Step 3 - Non-pharmacological Treatment

1. Exercise & Massage. Tender point thresholds are increased with exercise and external muscle stimulation via massage. Exercise has also been shown to decrease the perception of central pain, which is also increased in fibromyalgia patients. The following are recommended methods of exercise and pain control (Level I, II-2, Recommendation B)
    - Cardiovascular fitness training (Gowans & deHueck, 2004)
    - Muscle strengthening/stretching (Gowans & deHueck, 2004)
    - Balneotherapy (Evcik, Kizilay, & Gokcen, 2002)
    - Massage (Hadhazy et al., 2005)
    - Biofeedback (vanSanten et al., 2002)

Step 4 - Procedures. There have been very few studies of tender point or trigger point injection demonstrating its effectiveness. However, due to the complicated nature of pain management in some patients, it should not be ruled out as an alternative means of treatment. Further studies are warranted (Goldenberg, 2004). (Level III, Recommendation C)

Step 5 - Referrals. (for consideration). Referrals may be helpful for patients with severe symptoms and comorbid psychosocial issues, along with those who are non-compliant or who have not received adequate relief with medication therapy and management (Goldenberg, 2004). (Level III, Recommendation C)

- Sleep center
- Mental health professional
- Pain or rehabilitation clinic

Definitions:

Levels of Evidence

Level I: Evidence obtained from at least one properly randomized-controlled trial

Level II-1: Evidence obtained from well-designed control trials without randomization

Level II-2: Evidence obtained from well-designed cohort or case-controlled analytic studies, preferably from more than one center or research group

Level III: Opinions of respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees

Strength of Recommendations

A. There is good evidence to support the recommendation.
B. There is fair evidence to support the recommendation.
C. There is insufficient evidence to recommend for or against, but recommendations may be made on other grounds.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and graded for selected recommendations (see "Major Recommendations").

These recommendations were based primarily on sources such as national guidelines, meta-analysis review, and evidenced-based, randomized, controlled research studies. Guidelines and statements are synthesized to make them applicable to the treatment of fibromyalgia.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved identification of patients with fibromyalgia syndrome
- Improved treatment and management of patients with fibromyalgia syndrome
- Improved quality of life for patients with fibromyalgia syndrome
- Decreased cost of care
- Increased societal understanding and acceptance of fibromyalgia syndrome

POTENTIAL HARMS

Adverse side effects of medications

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These guidelines are not intended for use outside the stated population.
- The independent skill and judgment of the healthcare provider must always dictate treatment decisions.
- These practice guidelines are meant to serve as a general framework for managing clients with fibromyalgia syndrome. It may not always be appropriate to use these guidelines to manage clients because individual circumstances may vary. For example, different treatments may be appropriate for clients who are severely ill or who have comorbid, socioeconomic or other complicating conditions.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Texas, School of Nursing, Family Nurse Practitioner Program. Fibromyalgia treatment guideline. Austin (TX): University of Texas, School of Nursing; 2005 May. 13 p. [18 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 May

GUIDELINE DEVELOPER(S)

University of Texas at Austin School of Nursing, Family Nurse Practitioner Program - Academic Institution

SOURCE(S) OF FUNDING

University of Texas at Austin, School of Nursing, Family Nurse Practitioner Program

GUIDELINE COMMITTEE

Practice Guidelines Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Erin Brewerton, RN, MSN, FNP, Kim Miller, RN, MSN, FNP, Roxanne Nemec, RN, MSN, FNP, Mary Youngwith, RN, MSN, FNP

External Reviewer: Janet Morrison, RN, MSN, CNS

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available.

Print copies: Available from the University of Texas at Austin, School of Nursing. 1700 Red River, Austin, Texas, 78701-1499

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 28, 2005. The information was verified by the guideline developer on August 12, 2005.

COPYRIGHT STATEMENT

DISCLAIMER

NGC DISCLAIMER

Date Modified: 9/25/2006